DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 28, 2015

Limacorporate S.P.A.
Ms. Gabriele Calligaro
Via Nazionale, 52
33038 - Villanova di San Daniele
Udine, Italy

Re: K143256
Trade/Device Name: SMR Modular Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT
Dated: April 30, 2015
Received: May 1, 2015

Dear Ms. Calligaro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K143256

SMR Modular Glenoid
Indications for Use

The SMR Modular Glenoid and liner is intended for use in total primary or revision shoulder joint replacement with the SMR Anatomic Shoulder System.

The SMR Anatomic Shoulder System is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Revision of a failed primary implant;
- Cuff tear arthropathy (CTA Heads only).

The SMR Metal Backed Glenoid/Liner construct when used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Date: April 30, 2015

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Dr. Stephen J. Peoples
Principal Consultant
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Product	Common Name	Product Code	Regulation and Classification Name
SMR Modular Glenoid	Shoulder Prosthesis	KWS, KWT	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The L1 6mm liners are a line extension of the existing SMR Glenoid liners that are used with the SMR Modular Glenoid and SMR TT Metal Back Glenoid. These components are used in anatomic total shoulder replacements as part of the SMR Anatomic Shoulder System. When used for SMR anatomic shoulder replacement, the SMR Modular Glenoid and SMR TT Metal Back Glenoid are intended to be used with bone cement.

The L1 6mm liners are manufactured from UHMWPE (ISO 5834-2 – ASTM F648) and are available in four sizes (Small-R, Small, Standard and Large).

A snap-fit mechanism is used to attach the liner to the glenoid metal back component. Four protrusions on the upper surface of the metal-back glenoid and the conformity between the spherical shaped upper surface of the metal-back and back-side surface of the liner help ensure stability of the coupling.

The articulating surface has a radius of curvature greater than the corresponding humeral head allowing translation in the superior/inferior and anterior/posterior directions. The liners are intended to articulate with all Limacorporate SMR standard and CTA humeral heads. There is no restriction in regard to the pairing of different sizes of humeral heads and glenoid components and each humeral head size can be combined with each glenoid size.

Intended Use/Indications:

The SMR Modular Glenoid and liner is intended for use in total primary or revision shoulder joint replacement with the SMR Anatomic Shoulder System.

The SMR Anatomic Shoulder System is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;

- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Revision of a failed primary implant;
- Cuff tear arthropathy (CTA Heads only).

The SMR Metal Backed Glenoid/Liner construct when used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.

Predicate Devices:

- SMR Metal Back Glenoid and liners (Limacorporate, K113254);
- SMR TT Metal Back Glenoid and liners (Limacorporate, K133349);
- Bio-modular Shoulder System (Biomet, K030710).

Comparable Features to Predicate Device(s):

The new sizes of the liners are identical in design, materials, function, and intended use to the liners cleared in K113254 and K133349. Liner thicknesses are comparable to those available for K030710.

Non-Clinical Testing:

The L1 6mm liners were tested in static shear and dynamic testing. The testing results demonstrated the device's ability to fulfill the acceptance criteria imposed.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence of the L1 6mm liners to the existing liners of the SMR Modular Glenoid.